

## § 482.68

## 42 CFR Ch. IV (10–1–19 Edition)

maintaining optimal levels of physical and psychosocial functioning.

(2) The number of qualified therapists, support personnel, and consultants must be adequate to provide comprehensive therapeutic activities consistent with each patient's active treatment program.

[72 FR 60788, Oct. 26, 2007]

### § 482.68 Special requirement for transplant centers.

A transplant center located within a hospital that has a Medicare provider agreement must meet the conditions of participation specified in §§ 482.72 through 482.104 in order to be granted approval from CMS to provide transplant services.

(a) Unless specified otherwise, the conditions of participation at §§ 482.72 through 482.104 apply to heart, heart-lung, intestine, kidney, liver, lung, and pancreas centers.

(b) In addition to meeting the conditions of participation specified in §§ 482.72 through 482.104, a transplant center must also meet the conditions of participation in §§ 482.1 through 482.57, except for § 482.15.

[81 FR 64030, Sept. 16, 2016]

EFFECTIVE DATE NOTE: At 84 FR 51821, Sept. 30, 2019, § 482.68 was amended in the section heading by removing the phrase “transplant centers” and adding in its place the phrase “transplant programs”; and in the introductory text and in paragraph (b) by removing the phrase “transplant center” and adding in its place the phrase “transplant program”, effective Nov. 29, 2019.

### § 482.70 Definitions.

As used in this subpart, the following definitions apply:

*Adverse event* means an untoward, undesirable, and usually unanticipated event that causes death or serious injury, or the risk thereof. As applied to transplant centers, examples of adverse events include (but are not limited to) serious medical complications or death caused by living donation; unintentional transplantation of organs of mismatched blood types; transplantation of organs to unintended beneficiaries; and unintended transmission of infectious disease to a beneficiary.

*End-Stage Renal Disease (ESRD)* means that stage of renal impairment

that appears irreversible and permanent, and requires a regular course of dialysis or kidney transplantation to maintain life.

*ESRD Network* means all Medicare-approved ESRD facilities in a designated geographic area specified by CMS.

*Heart-Lung transplant center* means a transplant center that is located in a hospital with an existing Medicare-approved heart transplant center and an existing Medicare-approved lung center that performs combined heart-lung transplants.

*Intestine transplant center* means a Medicare-approved liver transplant center that performs intestine transplants, combined liver-intestine transplants, or multivisceral transplants.

*Network organization* means the administrative governing body to the network and liaison to the Federal government.

*Pancreas transplant center* means a Medicare-approved kidney transplant center that performs pancreas transplants alone or subsequent to a kidney transplant as well as kidney-pancreas transplants.

*Transplant center* means an organ-specific transplant program (as defined in this rule) within a transplant hospital (for example, a hospital's lung transplant program may also be referred to as the hospital's lung transplant center).

*Transplant hospital* means a hospital that furnishes organ transplants and other medical and surgical specialty services required for the care of transplant patients.

*Transplant program* means a component within a transplant hospital (as defined in this rule) that provides transplantation of a particular type of organ.

EFFECTIVE DATE NOTE: At 84 FR 51821, Sept. 30, 2019, § 482.70 was amended—

a. In the definition of “Adverse event” by removing the phrase “transplant centers” and adding in its place the phrase “transplant programs”;

b. By removing the definition of “Heart-Lung transplant center”;

c. By adding definitions for “Heart-Lung transplant program” and “Intestine transplant program” in alphabetical order;

d. By removing the definition of “Intestine transplant center”;

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- e. By adding a definition for “Intestine transplant program” in alphabetical order;
- f. By removing the definition of “Pancreas transplant center”;
- g. By adding a definition for “Pancreas transplant program” in alphabetical order;
- h. By removing the definition of “Transplant center”;
- i. By revising the definition of “Transplant program”.

The amendments are effective Nov. 29, 2019. For the convenience of the user, the added and revised text is set forth as follows:

### § 482.70 Definitions.

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*Heart-Lung transplant program* means a transplant program that is located in a hospital with an existing Medicare-approved heart transplant program and an existing Medicare-approved lung program that performs combined heart-lung transplants.

*Intestine transplant program* means a Medicare-approved liver transplant program that performs intestine transplants, combined liver-intestine transplants, or multivisceral transplants.

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*Pancreas transplant program* means a Medicare-approved kidney transplant program that performs pancreas transplants alone or subsequent to a kidney transplant as well as kidney-pancreas transplants.

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*Transplant program* means an organ-specific transplant program within a transplant hospital (as defined in this section).

### GENERAL REQUIREMENTS FOR TRANSPLANT CENTERS

### § 482.72 Condition of participation: OPTN membership.

A transplant center must be located in a transplant hospital that is a member of and abides by the rules and requirements of the Organ Procurement and Transplantation Network (OPTN) established and operated in accordance with section 372 of the Public Health Service (PHS) Act (42 U.S.C. 274). The term “rules and requirements of the OPTN” means those rules and requirements approved by the Secretary pursuant to § 121.4 of this title. No hospital that provides transplantation services shall be deemed to be out of compliance with section 1138(a)(1)(B) of the Act or this section unless the Sec-

retary has given the OPTN formal notice that he or she approves the decision to exclude the transplant hospital from the OPTN and also has notified the transplant hospital in writing.

EFFECTIVE DATE NOTE: At 84 FR 51822, Sept. 30, 2019, § 482.72 was amended by removing the words “transplant center” and adding in their place the words “transplant program”, effective Nov. 29, 2019.

### § 482.74 Condition of participation: Notification to CMS.

(a) A transplant center must notify CMS immediately of any significant changes related to the center’s transplant program or changes that could affect its compliance with the conditions of participation. Instances in which CMS should receive information for follow up, as appropriate, include, but are not limited to:

(1) Change in key staff members of the transplant team, such as a change in the individual the transplant center designated to the OPTN as the center’s “primary transplant surgeon” or “primary transplant physician;”

(2) Termination of an agreement between the hospital in which the transplant center is located and an OPO for the recovery and receipt of organs as required by section 482.100; and

(3) Inactivation of the transplant center.

(b) Upon receiving notification of significant changes, CMS will follow up with the transplant center as appropriate, including (but not limited to):

(1) Requesting additional information;

(2) Analyzing the information; or

(3) Conducting an on-site review.

[72 FR 15273, Mar. 30, 2007, as amended at 79 FR 27155, May 12, 2014]

EFFECTIVE DATE NOTE: At 84 FR 51822, Sept. 30, 2019, § 482.74 was amended in paragraph (a) introductory text by removing the words “transplant center” and “center’s” and adding in their place the words “transplant program” and “hospital’s”, respectively; in paragraph (a)(1) by removing the words “transplant center” and “center’s” and adding in their place the words “transplant program” and “program’s”, respectively; and in paragraphs (a)(2) and (3) and (b) introductory text by removing the words “transplant center” and adding in their place the words “transplant program”, effective Nov. 29, 2019.